Remarks

Reconsideration of this application, as amended, is respectfully requested. Claims 1, 2, 5-7, 11-13, 17, 20, and 24-27 have been amended. Claims 4, 22, and 29 have been cancelled. New claims 30-42 have been added. With this amendment, claims 1-3, 5-7, 11-17, 20, 24-27, and 30-42 are pending. No new matter is added with these amendments which are made without prejudice or disclaimer. Applicants reserve the right to prosecute any cancelled or otherwise unclaimed subject matter in this or a separate application, as appropriate. . Consideration and entry of these remarks and amendments is respectfully requested.

I. Rejections Under 35 U.S.C. § 102(a)

A. Rejection of claims 1-7, 13, 16, and 17 as anticipated by "Barnardo I"

Claims 1-7, 13, 16 and 17 stand rejected under 35 U.S.C. 102(a) as being anticipated by Barnardo et al. ("Detection of HLA antibodies using single recombinant HLA alleles", Human Immunology, Abstracts 1999, Vol. 60, Suppl. 2; hereinafter referred to as "Barnardo I". The rejection is moot as to cancelled claim 4. Applicants respectfully traverse the remaining rejections as indicated below.

Applicants respectfully maintain that Barnardo I is not prior art. It is only "where an inventor publishes more than one year before filing [that] he or she forecloses obtaining a patent on an invention that would have been obvious from the publication...." In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988). Applicants' priority date of March 17, 2000 is prior to the expiration of one year from the publication date of Barnardo I. As stated by Martin Barnardo in his declaration submitted with this response: 1) Graham Ogg was named on Barnardo I only for providing HLA class I monomers consisting of the various heavy chains complexed with the beta-2-microglobulin and various peptides, and is not an inventor of the instantly claimed subject matter; and, 2) Olivia Shaw was named on Barnardo I for carrying out technical work under the direction of Andrea Harmer and being otherwise helpful in completing the project, and is not an inventor of the instantly claimed subject matter. As such, the subject matter of the Barnardo I abstracts was not developed "by others", and is not prior art. Accordingly, then, the rejection based on Barnardo I is improper and its withdrawal is respectfully requested.

B. Rejection of claims 1-7, 13, 16, and 17 as anticipated by "Barnardo II"

Claims 1-7, 13, 16 and 17 stand rejected under 35 U.S.C. 102(a) as being anticipated by Barnardo et al. ("Detection of HLA-specific IgG using single, recombinant HLA alleles", Human Immnology (1999) Vol 60., No. Suppl. 1, pp. S1; hereinafter referred to as "Barnardo II"). The rejection is moot as to cancelled claim 4. Applicants respectfully traverse the remaining rejections as indicated below.

Applicants respectfully maintain that Barnardo II is not prior art. It is only "where an inventor publishes more than one year before filing [that] he or she forecloses obtaining a patent on an invention that would have been obvious from the publication...." In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988). Applicants' priority date of March 17, 2000 is prior to the expiration of one year from the publication date of Barnardo II. As stated by Martin Barnardo in his declaration submitted with this response: 1) Michael Bunce is an inventor of the instantly claimed subject matter, should have been listed as an author of Barnardo II, and was only omitted by mistake; 2) Graham Ogg was named on Barnardo II only for providing HLA class I monomers consisting of the various heavy chains complexed with the beta-2-microglobulin and various peptides, and is not an inventor of the instantly claimed subject matter. As such, the subject matter of Barnardo II was not developed "by others", and is not prior art. Accordingly, then, the rejection based on Barnardo II is improper and its withdrawal is respectfully requested.

II. <u>Rejections Under 35 U.S.C. § 103(a)</u>

A. Rejection of claims 1-7 and 11-17 over Lee, Chang, and Walter

Claims 1-7 and 11-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (U.S. Pat. No. 5,948,627) in view of Chang et al. (U.S. Pat. No. 5,270,169) and further in view of Walter et al. (Int. Immunol., Vol. 9, No. 3, pp. 451-459, 1997). The rejection is moot as to cancelled claim 4. Applicants respectfully traverse the remaining rejections as indicated below.

As amended, the claims 1-3, 5-7, and 11-17 relate to a method for detecting the presence of antibodies reactive to particular MHC (claim 1) or HLA (claim 2) alleles. The claimed method requires contacting a body fluid sample (e.g., blood or serum) with a

recombinant MHC or HLA molecule representing a particular allele such that antibodies binding to one allele may be identified separately from antibodies reactive to any other allele (e.g, the "one well, one antigen" format; see the instant specification at para. [0077]). To accomplish this, the recombinant MHC or HLA molecules are bound to discrete sites upon a single solid support so that the antibodies reactive with individual MHC or HLA alleles may be detected. Applicants respectfully maintain that the combined cited art does not render the instantly amended claims obvious.

The Examiner alleges that modification of Lee's methodology (which does not use recombinant MHC or HLA) as "suggested" by Chang (e.g., that one could use "synthetic HLA") in view of Walter's disclosure of recombinant HLA and antibodies binding thereto, renders the instantly claimed methods obvious. However, simple substitution of the cell-derived "purified HLA" of Lee with the recombinant HLA of Walter (e.g., as allegedly suggested by Chang) does not lead the skilled artisan to the instantly claimed invention. Lee does not suggest nor produce a bead representing a single allele, or provide any guidance as to how recombinant MHC or HLA molecules could be directed to a "discrete site" on a solid support. In each of Examples 1-5, Lee simply coats beads with "HLA antigen preparations...purified from Epstein Barr virus transformed lymphocyte cell lines" by "passive absorption". One of skill in the art would understand this to mean that the beads are randomly coated with whichever HLA molecules are expressed by the source lymphocyte. Lee does not provide any method to direct HLA molecules representing particular alleles to discrete sites on a solid support, as instantly claimed. And neither Chang's reference to a "gene product of a cloned HLA gene" nor Walter's disclosure of recombinant HLA molecules cures the deficiencies of Lee. It was not until the Applicant's conceived of and tested the instantly claimed method that the skilled artisan had any reasonable expectation of success in practicing the same. Accordingly, Applicants do not believe this combination of references renders the subject matter of the instant claims obvious. It is therefore respectfully requested that these rejections be withdrawn.

B. Rejection of claim 12 over Barnardo I or Barnardo II in view of Pouletty

Claim 12 stands rejected under 35 U.S.C. § 103(a) over Barnardo (Supplement 2; "Barnardo I") or Barnardo (Suppl. 1, pp. S1; "Barnardo II")) in view of Pouletty et al. (U.S. Pat. No. 5,292,641). Applicants respectfully disagree and traverse these rejections. As indicated above, Applicants believe that neither Barnardo I nor Barnardo II are available as prior art under 35 U.S.C. § 103. As such, Applicants respectfully maintain that rejection is improper and request its withdrawal.

C. Rejection of claims 14 and 15 over Barnardo I or Barnardo II in view of Baserga et al. (U.S. Pat. No. 6,218,363)

Claims 14 and 15 stand rejected under 35 U.S.C. § 103(a) over Barnardo (Supplement 2; "Barnardo I") or Barnardo (Suppl. 1, pp. S1; "Barnardo II")) in view of Baserga et al. (U.S. Pat. No. 6,218,363). Applicants respectfully disagree and traverse these rejections as indicated below. As indicated above, Applicants believe that neither Barnardo I nor Barnardo II are available as prior art under 35 U.S.C. § 103. As such, Applicants respectfully maintain that rejection is improper and request its withdrawal.

D. Rejection of claims 20, 22, 24-27 and 29 over either Barnardo reference and Boguslaski

Claims 20, 22, 24-27 and 29 stand rejected under 35 U.S.C. § 103(a) over Barnardo (Supplement 2; "Barnardo I") or Barnardo (Suppl. 1, pp. S1; "Barnardo II")) in view of Boguslaski et al. (U.S. Pat. No. 5,420,016). The rejection is moot as to cancelled claims 22 and 29. As to the remaining claims, Applicants believe (as indicated above) that neither Barnardo I nor Barnardo II are available as prior art under 35 U.S.C. § 103. As such, Applicants respectfully maintain that rejection is improper and request its withdrawal.

E. Rejection of claims 20, 22, 24 and 29 over Lee, Chang, Walter, and Boguslaski

Claims 20, 22, 24 and 29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (U.S. Pat. No. 5,948,627) in view of Chang et al. (U.S. Pat.

No. 5,270,169) and Walter et al. (Int. Immunol., Vol. 9, No. 3, pp. 451-459, 1997), and further in view of Boguslaski et al. (5,420,016). The rejection is moot as to cancelled claims 22 and 29. As described above, Applicants believe the rejection of claims 1-7 and 11-17 is improper as the combination of Lee, Chang and Walter do not render the claims obvious. Boguslaski's alleged assembly of test kits does not cure the deficiencies of this combination of references. As such, Applicants respectfully maintain that rejection is improper and request its withdrawal.

F. Rejection of claims 25-27 over Lee, Chang, Walter, Boguslaski and Luxemborg

Claims 25-27 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lee et al. (U.S. Pat. No. 5,948,627) in view of Chang et al. (U.S. Pat. No. 5,270,169), Walter et al. (Int. Immunol., Vol. 9, No. 3, pp. 451-459, 1997), and Boguslaski et al. (5,420,016), and further in view of Luxemborg et al. (U.S. Pub. No. 2004/0137617). As described above, Applicants believe the rejection of claims 1-7 and 11-17 is improper as the combination of Lee, Chang and Walter does not render the claims obvious. Luxemborg's alleged disclosure of biotinylated MHC molecules does not cure the deficiencies of this combination of references. As such, Applicants respectfully maintain that rejection is improper and request its withdrawal.

Conclusions

Applicants believe that a full and complete Reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned. Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

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